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EXAMINER	
BAXTER, ZOE E	
ART UNIT	PAPER NUMBER
3735	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/01/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/520,273	SCHNALL, ROBERT P	
	Examiner	Art Unit	
	Zoe E. Baxter	3735	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-63* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-31,33-44,49-53,55-60,62 and 63* is/are rejected.

7)☒ Claim(s) *32,45-48,54 and 61* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *18 January 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1/10/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. The terms "relatively restricted area" and "small fraction" in claim 2 are relative terms, which renders the claim indefinite. The terms "relatively restricted area" and "small fraction" are not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-4, 8, 10, 12, 17, 18-20, 22, 24-30, 33, 34, 44, 49-53, 55-60, 62 and 63 are rejected under 35 U.S.C. 102(b) as being anticipated by Goor et al. (PCT/IL97/00249).

5. Referring to claim 1 Goor et al. '249 teach a probe for application to a selected area of a subject's skin covering a body part, which selected area serves as a measurement site for measuring changes in the pulsatile arterial blood volume (page 25 lines 17-32) comprising: a base for application to the selected area of the subject's skin

at said measurement site (figure 1 reference 3); a pressure applicator carried by said base for applying a static pressure to the subject's skin at said measurement site when said base is applied thereto (page 28 lines 17-29); and a sensor carried by said pressure applicator for sensing changes in the pulsatile arterial blood volume at said measurement site when the base is applied thereto (page 45 line 30-page 46 line 8); said pressure applicator being designed to apply to said measurement site, when the base is applied thereto, a static pressure of a sufficient magnitude to partially unload the wall tension of, but not to occlude, the arteries at said measurement site (page 28 line 29- page 29 line 3); said pressure applicator being configured to substantially prevent venous distention and blood pooling at said measurement site by applying sufficient external counter pressure to effectively collapse the underlying veins and limit the local venous blood flow to the arterial throughout while permitting free venous drainage with respect to said measurement site through tissues surrounding said measurement site(page 28 lines 17-28).

6. Referring to claim 2 Goor et al. '249 teach a probe for measuring arterial blood volume, wherein said pressure applicator is configured to apply said static pressure to a relatively restricted area of the subject's skin, which area occupies a relatively small fraction of the surface perimeter of the respective body part at said measurement site, to thereby permit free venous drainage from said measurement site via a wide region of unrestricted passageways surrounding the measurement site (page 28 lines 17-28). It is interpreted by the examiner that a finger is a relatively restricted area of the subject's skin and a finger occupies a relatively small fraction of the surface perimeter of an arm.

7. Referring to claim 3 Goor et al. '249 teach a probe for measuring arterial blood volume, wherein said pressure applicator applies to said measurement site a static pressure which is above the subject's local venous pressure and slightly below the subject's diastolic blood pressure (page 29 lines 1-7). It is well known to one of ordinary skill in the art that the normal blood pressure of a human is 120/80mmhg. The 80mmHg is the diastolic pressure and Goor et al. '249 teach that the pressure in the probe can be 30mmHg, which is slightly below the normal diastolic blood pressure of a human.

8. Referring to claim 4 Goor et al. '249 teach a probe for measuring arterial blood volume, wherein said pressure applicator comprises a fluid chamber (figure 9 reference 5 and 43) and an external source of fluid for applying said static pressure to said measurement site (figure 9 reference 10).

9. Referring to claim 8 Goor et al. '249 teach a probe for measuring arterial blood volume, wherein said pressure applicator comprises a resilient elastomeric material for applying said static pressure to said measurement site (page 26 lines 28-31).

10. Referring to claim 10 Goor et al. '249 teach a probe for measuring arterial blood volume, wherein said base is of a relatively non-stretchable material (page 26 line 21) and carries said pressure applicator (figure 11 reference 4) and sensor at the center thereof (figure 11 reference number 100).

11. Referring to claim 12 Goor et al. '249 teach a probe for measuring arterial blood volume, wherein said probe includes an optical sensor for sensing the blood oxygen saturation level (page 45 lines 23-29).

12. Referring to claim 17 Goor et al. '249 teach a probe for measuring arterial blood volume, in combination with a clamping device for applying a clamping force to said

base of the probe when applied to said measurement site, and a counter-force to the respective body part of the subject at the opposite side of said measurement site (page 36 lines 6-21). Goor et al. '249 describe the clamping device as a restrainer bar.

13. Referring to claim 18 Goor et al. '249 teach an apparatus for detecting and indicating a medical condition or a change in physiological state of a subject (page 38 lines 31-33), comprising: a probe according to claim 1 for application to a measurement site on the subject's skin and for producing an output corresponding to measured changes in the pulsatile arterial blood volume thereat (page 39 line 3); and a data processor system for utilizing said measured changes to detect and indicate a medical condition or change in physiological state of the subject (page 40 lines 5-13).

14. Referring to claim 19 Goor et al. '249 teach an apparatus for detecting a medical condition, wherein said data processor system utilizes said measured changes in pulsatile arterial volume to indicate the peripheral arterial tone of the subject (page 45 lines 5-22).

15. Referring to claim 20 Gorr et al. teach an apparatus for detecting a medical condition, wherein said data processor system utilizes said measured changes in pulsatile arterial volume to indicate changes in the systemic blood pressure of the subject (page 63 lines 17-26). By acquiring a continuous blood pressure it is inherent that a systolic blood pressure is also being measured.

16. Referring to claim 22 Goor et al. '249 teach an apparatus, wherein said data processor system utilizes said measured changes in the pulsatile arterial blood volume to indicate the level of vascular tone at the measurement site (page 45 lines 5-22).

17. Referring to claim 24 Goor et al. '249 teach an apparatus for detecting a medical condition, wherein said apparatus further comprises at least one additional probe for application to at one additional measurement site on the subject's skin and for measuring changes in the pulsatile arterial blood volume thereat; said data processor system utilizing the measured changes of both of said probes for detecting and indicating the medical condition or the change in physiological state of the subject (page 37 line 27-page 38 line 8).

18. Referring to claims 25-27, as to the language, "constructed for application to measurement sites in which..." the applicant(s) should note that this is merely "intended use" language, which cannot be relied upon to define over the prior art since Goor et al., teaches all of the claimed structural elements and their recited relationships.
The probes taught by Goor et al. '249 are clearly able to be applied to the measurement sites stated by the applicant.

19. Referring to claim 28 as to the language "constructed for application to measurement sites in which the pulsatile volume of the vascular beds are respectively predominantly affected by autonomic nervous system activity or by the level of systemic blood pressure", the applicant(s) should note that this is merely "intended use" language which cannot be relied upon to define over the prior art since Goor et al. '249 teaches all of the claimed structural elements and their recited relationships. The probes taught by Goor et al. '249 are clearly able to be applied to the measurement site. Goor et al further teach the data processor system compares the outputs of said probes to indicate the medical condition or change in physiological state of the subject (page 37 line 27-page 38 line 8).

20. Referring to claim 29 as to the language "constructed for application to measurement sites in which the pulsatile volume of the vascular beds are unequally affected by autonomic nervous system activity", the applicant(s) should note that this is merely "intended use" language which cannot be relied upon to define over the prior art since Goor et al. '249 teaches all of the claimed structural elements and their recited relationships. The probes taught by Goor et al. '249 are clearly capable of being applied to the measurement site. Goor et al. '249 further teaches a data processor which compares the outputs of said probes to indicate the medical condition or change in physiological state of the subject (page 37 line 27-page 38 line 8).

21. Referring to claim 30, as to the language "constructed for application to measurement sites in which pulsatile volume of the vascular beds are respectively predominantly affected by unequal levels of autonomic nervous system activity", the applicant(s) should note that this is merely "intended use" language which cannot be relied upon to define over the prior art since Goor et al. '249 teaches all of the claimed structural elements and their recited relationships. The probes taught by Goor et al. '249 are clearly capable of being applied to the measurement site. Goor et al. '249 further teach a data processor which compares the outputs of said probes to indicate the medical condition or change in physiological state of the subject.

22. Referring to claim 33 Goor et al. '249 teach a method of detecting and indicating a medical condition or change in physiological state of a subject, comprising: applying a probe according to claim 1 to a measurement site on the subject's skin for measuring changes in the pulsatile arterial blood volume thereat; and utilizing said measured

changes to detect and indicate a medical condition or change in physiological state of the subject (page 18 lines 21-34).

23. Referring to claim 34 Goor et al. '249 teach a method of detecting and indicating a medical condition, wherein said probe is applied to a relatively restricted area of the subject's skin substantially overlying a medium to large sized artery (page 27 lines 15-23). It is noted that Goor et al. '249 teach the probe can be placed on any of the fingers or toes; a thumb is a finger comprising a medium sized artery.

24. Referring to claim 44 Goor et al. '249 teach a method of detecting and indicating a medical condition, wherein at least one additional probe is applied to at least an additional measurement site on the subject's skin for measuring the pulsatile arterial blood volume thereat, the measurement of the additional probe(s) at the additional measurement site(s) also being utilized for detecting and indicating the medical condition or change in physiological state of the subject (page 37 line 27-page 14 line 8).

25. Referring to claim 49 Goor et al. '249 teach a probe for measuring arterial blood volume, wherein the sensing modality for sensing changes in the pulsatile arterial blood volume at said measurement site is the pressure change within the said pressure applicator (page 39 lines 17-31).

26. Referring to claim 50 Goor et al. '249 teach a probe for measuring arterial blood volume, wherein a multiplicity of different sensors are used for sensing changes in the pulsatile arterial blood volume at said measurement site (page 39 lines 17-31).

27. Referring to claim 51 Goor et al. '249 teach a method of detecting and indicating a medical condition, wherein said probe is applied over a skin region predominantly

containing microvascular blood vessels for deriving a signal for biofeedback input (page 42 lines 16-22). The biofeedback input into an alarm.

28. Referring to claim 52 Goor et al. '249 teach a method of detecting and indicating a medical condition, wherein said probe is applied over a skin region overlying a superficial conducting artery for deriving a signal for biofeedback input (page 42 lines 16-22).

29. Referring to claim 53 Goor et al. '249 teach a method wherein the probe is applied over the skin in a region predominantly containing microvascular blood vessels for deriving a signal in response to a physical stressor (page 42 lines 16-22). The act of applying pressure to the region by the probe is a physical stressor.

30. Referring to claim 55 Goor et al. '249 teach a method of detecting and indicating a medical condition, wherein said detecting comprises viewing time-course of a peripheral arterial tone signal (figure 12).

31. Referring to claim 56 Goor et al. '249 teach a method of detecting and indicating a medical condition, wherein said detecting comprises viewing variations in a peripheral arterial tone signal (page 53 line 17-page 54 line1).

32. Referring to claim 57 Goor et al. '249 teach a method of detecting and indicating a medical condition, wherein a multiplicity of different sensors are used for detecting changes in the pulsatile arterial blood volume at said measurement sites (page 39 lines 17-31).

33. Referring to claim 58 Goor et al. '249 teach a method of detecting and indicating a medical condition, wherein detecting of changes in the pulsatile arterial blood volume

at said measurement sites is performed for deriving a signal for biofeedback input (page 42 lines 16-22).

34. Referring to claim 59 Goor et al. '249 teach a method of detecting and indicating a medical condition, wherein detecting changes in the pulsatile arterial blood volume at a measurement site is performed for deriving a signal in response to a physical stimulus, the physical stimulus being a pressure applied by the probe (page 42 lines 16-22).

35. Referring to claim 60 Goor et al. '249 teach a method of detecting and indicating a medical condition, wherein detecting changes in the pulsatile arterial blood volume at said measurement sites comprises viewing time-course of a peripheral arterial tone signal (page 42 lines 2-15).

36. Referring to claim 62 Goor et al. '249 teach a probe for measuring arterial blood volume, wherein pressure applied by said pressure applicator extends in area beyond the region of said sensor to extend the effective boundary of the pressure field overlying the sensing region, to substantially prevent venous distention and blood pooling at said measurement site and extended effective boundary of the pressure field by applying sufficient external counter pressure to effectively collapse the underlying veins and limit the local venous blood flow to the arterial throughput while permitting free venous drainage with respect to said measurement site through tissues surrounding said measurement site (page 28 lines 17-28).

37. Referring to claim 63 Goor et al. '249 teach an apparatus for measuring arterial blood volume, further including a sleep/wake detector, wherein said data processor

system utilizes said measured changes to indicate the sleep/wake status of the subject (page 53 lines 17-28).

38. Claims 1, 5, 11, 18 and 23 are rejected under 35 U.S.C. 102(b) as being anticipated by Schnall (PCT/IL99/00292).

39. Referring to claim 1 Schnall teaches a probe for application to a selected area of a subject's skin covering a body part, which selected area serves as a measurement site for measuring changes in the pulsatile arterial blood volume thereat (page 1 lines 10-16), comprising: a base for application to the selected area of the subject's skin at said measurement site (figure 1 reference 8); a pressure applicator carried by said base for applying a static pressure to the subject's skin at said measurement site when said base is applied thereto (page 7 lines 31-33); and a sensor carried by said pressure applicator for sensing changes in the pulsatile arterial blood volume at said measurement site when the base is applied thereto (page 7 lines 10-14); said pressure applicator being designed to apply to said measurement site, when the base is applied thereto, a static pressure of a sufficient magnitude to partially unload the wall tension of, but not to occlude, the arteries at said measurement site; said pressure applicator being configured to substantially prevent venous distention and blood pooling at said measurement site by applying sufficient external counter pressure to effectively collapse the underlying veins and limit the local venous blood flow to the arterial throughput while permitting free venous drainage with respect to said measurement site through tissues surrounding said measurement site (page 2 line 22-page 3 line 11).

40. Referring to claim 5 Schnall teaches a probe for measuring arterial blood volume, wherein said pressure applicator comprises a fluid chamber with at least one elastic wall

constructed to utilize Laplace's law and including a self-contained fluid for applying said static pressure to said measurement site such that the level of pressure applied by said probe is substantially unaffected by the mechanical characteristics of the underlying tissues (page 8 lines 8-24).

41. Referring to claim 11 Schnall teaches a probe for measuring arterial blood volume, wherein said base includes an adhesive layer on its surface facing the pressure applicator and sensor for adhering the base to the subject's skin at the measurement site (page 18 lines 31-40).

42. Referring to claim 18 Schnall teaches an apparatus for detecting and indicating a medical condition or a change in physiological state of a subject, comprising: a probe for application to a measurement site on the subject's skin and for producing an output corresponding to measured changes in the pulsatile arterial blood volume thereat; and a data processor system for utilizing said measured changes to detect and indicate a medical condition or change in physiological state of the subject (page 18 lines 12-25).

43. Referring to claim 23 Schnall teach an apparatus for detecting and indicating a medical condition or a change in physiological state of a patient, wherein said sensor is an optical sensor, and said data processor system utilizes said measured changes in pulsatile arterial volume to produce a measurement of the oxygen saturation level of the blood (page 21 line 30-page 22 line 2).

Claim Rejections - 35 USC § 103

44. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

45. Claims 6, 7 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goor et al. '249 as applied to claim 1 above, and further in view of Davis et al. (PGPUB US 2002/0188206 A1).

46. Referring to claim 6 Goor et al. '249 fail to teach a probe wherein the pressure applicator comprises a chamber including a spring for applying pressure to the measurement site. Davis et al. teach a probe; wherein said pressure applicator comprises a chamber including a spring therein for applying said static pressure to said measurement site (page 10 paragraph 0112). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the invention of Goor et al. '249 to include a probe similar to that of Davis et al. in order to provide uniform pressure generation (Davis et al. page 10 paragraph 0112).

47. Referring to claim 7 Davis et al. teach a probe, wherein said spring for applying said static pressure to said measurement site is of a relatively large uncompressed length such that the effective pressure generated by it when it is compressed is substantially unaffected by relatively small variations in compressed length due to the mechanical characteristics of the underlying tissues (page 10 paragraph 0112). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the invention of Goor et al. '249 to include a probe similar to that of Davis et al. in order to provide uniform pressure generation (Davis et al. page 10 paragraph 0112).

48. Referring to claim 9 Davis et al. teach a probe, wherein said resilient elastomeric material for applying said static pressure to said measurement site is of a relatively large uncompressed length such that the effective pressure generated by it, when it is compressed, is substantially unaffected by relatively small variations in compressed length due to the mechanical characteristics of the underlying tissues (page 10 paragraph 0112). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the invention of Goor et al. '249 to include a probe similar to that of Davis et al. in order to provide uniform pressure generation (Davis et al. page 10 paragraph 0112).

49. Claims 13 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goor et al. '249 as applied to claim 12, in view of Mills (PGPUB US 2003/0109772 A1).

50. Referring to claim 13 Goor et al. '249 fail to teach a probe for measuring arterial blood volume, wherein said probe also includes an electrode for sensing an electrical potential such as the electrocardiograph (ECG) signal of the subject. Mills teaches a probe comprising an electrode for sensing an electrical potential such as ECG (page 6 paragraph 0106). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the invention of Goor et al. '249 to include an electrode similar to that of Mills in order to measure central and peripheral pulse wave velocities as well as ECG (Mills page 6 paragraph 0106).

51. Referring to claim 14 Goor et al. '249 fail to teach a probe for measuring arterial blood volume, wherein said probe also includes an electrode for sensing an electrical potential such as the electrocardiograph (ECG) signal of the subject. Mills teaches a

probe comprising an electrode for sensing an electrical potential such as ECG (page 6 paragraph 0106). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the invention of Goor et al. '249 to include an electrode similar to that of Mills in order to measure central and peripheral pulse wave velocities as well as ECG (Mills page 6 paragraph 0106).

52. Claims 15 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goor et al. '249 as applied to claim 1 above, and further in view of Ogura et al. (PGPUB US 2001/0003792 A1).

53. Referring to claim 15 Goor et al. '249 fail to teach a probe for measuring arterial blood volume comprising an acoustic sensor. Ogura et al. teach a probe comprising an acoustic sensor (page 4 paragraph 0031). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the invention of Goor et al. '249 to include an acoustic sensor in order to provide a heartbeat-synchronous-pulse sensor (Ogura et al. page 4 paragraph 0031).

54. Referring to claim 16 Goor et al. '249 fail to teach a probe for measuring arterial blood volume comprising an acoustic sensor. Ogura et al. teach a probe comprising an acoustic sensor (page 4 paragraph 0031). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the invention of Goor et al. '249 to include an acoustic sensor in order to provide a heartbeat-synchronous-pulse sensor (Ogura et al. page 4 paragraph 0031).

55. Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Goor et al. '249 as applied to claim 18 above, and further in view of Spencer (US Patent No. 4164937). Goor et al. '249 fail to teach an apparatus wherein the data processor

system utilizes measured changes in pulsatile arterial volume to indicate the pulse rate of the subject. Spencer teaches the detection of pulsatile blood volume changes to provide a corresponding pulse rate (column 1 lines 58-68). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the invention of Goor et al. '249 to include a processor, which indicates the pulse rate similar to that of Spencer in order to help evaluate the condition of the subject (Spencer column 1 lines 25-26).

56. Claim 31 is rejected under 35 U.S.C. 103(a) as being unpatentable over Goor et al. '249 as applied to claim 24 above, and further in view of Sramek (US Patent No. 4807638). Goor et al. '249 fail to teach an apparatus wherein the data processor system utilizes the outputs of two probes for indicating the pulse propagation velocity. Sramek teaches a system which measures pulse propagation velocity using the distance between two sensors (column 14 lines 50-69). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the invention of Goor et al. '249 to include a pulse propagation velocity calculation similar to that of Sramek in order to provide more patient data.

57. Claims 35 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goor et al. '249. Goor et al. '249 do not disclose expressly a method, wherein a probe is applied to a relatively restricted area of the subject's skin, which is relatively rich or poor in arteriovenous anastamoses vessels. At the time of the invention, it would have been an obvious design choice to a person of ordinary skill in the art to apply the probe to an area of relatively rich or poor arteriovenous anastamoses vessels since neither provides an advantage, is used for a purpose or solves a stated problem. One

of ordinary skill in the art would have expected the probe taught by Goor et al. '249 to perform equally well. Therefore it would have been prima facie obvious to modify the probe of Goor et al. '249 to obtain the invention as specified in claims 35 and 36 because such a modification would have been considered a mere design consideration which fails to patentably distinguish over the prior art of Goor et al. '249

58. Claims 37, 38 and 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goor et al. '249 in view of Niwa. Niwa teaches that a probe can be placed on the wrist of the subject. Niwa fails to disclose expressly that the probe can be placed on the subject's forehead, forearm, palm of the hand or sole of the foot. At the time of the invention it would have been an obvious matter of design choice to a person of ordinary skill in the art to apply the probe to a subject's forehead, forearm, palm of the hand or sole of the foot since neither provides an advantage, is used for a purpose or solves a stated problem. One of ordinary skill in the art would have expected the probe taught by Niwa to perform equally well. Therefore it would have been prima facie obvious to modify the probe of Niwa to obtain the invention as specified in claims 37, 38 and 40 because such a modification would have been considered a mere design consideration which fails to patentably distinguish over the prior art of Niwa.

59. Claim 39 is rejected under 35 U.S.C. 103(a) as being unpatentable over Goor et al. '249 as applied to claim 33 above, and further in view of Niwa (US Patent No. 5238000). Goor et al. '249 fail to teach a method, wherein said probe is applied to a relatively restricted area of the subject's skin at the subject's wrist. Niwa teach a probe attached to the subject's wrist (column 5 lines 23-31). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the invention of Goor

et al. '249 to include a probe similar to that of Niwa in order to place the sensor in close proximity to a vascular region.

60. Claim 41 is rejected under 35 U.S.C. 103(a) as being unpatentable over Goor et al. '249 as applied to claim 33 above, and further in view of Davis et al. (Patent No. US 6749567 B2). Goor et al. '249 fail to teach a method wherein the data processor system utilizes measured changes in arterial volume to produce a measurement of the oxygen saturation level of the blood. Davis et al. teach it is well known to one of ordinary skill in the art that plethysmograph measures a change in volume and records a changing value such as oxygen saturation of blood (column 5 line 66-column 6 line 23). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the invention of Goor et al. '249 to include an oxygen saturation level similar to that of Davis et al. in order to better diagnose the patient.

61. Claims 42 and 43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goor et al. '249 as applied to claim 33 above, and further in view of Goor et al. '249 (Patent No. US 6322515 B1). Goor et al. '249 fail to teach an evaluation of endothelial function. Goor et al. '515 teach an evaluation of endothelial function based on the pulse arterial tone (column 35 lines 16-29) and arterial tone can be evaluated by monitoring blood volume (column 11 lines 10-23). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the invention of Goor et al. '249 to include endothelial function evaluation similar to that of Goor et al. '515 in order to provide a non-invasive apparatus enabling accurate and consistent detection of medical conditions (Goor et al. '515 column 10 lines 56-61).

Allowable Subject Matter

62. Claims 32, 45-48, 54 and 61 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

63. Referring to claim 32 prior art of record fail to teach or fairly suggest an apparatus, wherein at least one of two probes includes an electrode for sensing the electrocardiograph (ECG) signal of a subject; and wherein said data processor system utilizes said measured changes in the pulsatile arterial blood volume, and said ECG signal, to determine the pulse transit time and/or pulse propagation velocity.

64. Referring to claim 45 prior art of record fail to teach or fairly suggest a method of determining arterial blood volume, wherein two probes are applied to measurement sites in which the vascular beds thereat have different levels of reactivity to autonomic stimulation.

65. Referring to claim 46 prior art of record fail to teach or fairly suggest a method, wherein two probes are applied to measurement sites in which the vascular beds thereof have different responses to reflex eliciting events.

66. Referring to claim 47 prior art of record fail to teach or fairly suggest a method, wherein at least two probe respectively include an electrode for sensing the electrocardiograph (ECG) signal of the subject, and wherein said probes are applied to measurement sites at a known distance from each other and the measured changes of said probes are utilized for indicating the pulse transit time and the pulse propagation velocity.

67. Referring to claim 48 prior art of record fail to teach or fairly suggest a method, wherein one of two probes are applied to a subject's body surface overlying a superficial conducting artery, and another of said probes is applied to a subject's body surface overlying a predominantly microcirculatory vascular bed.

68. Referring to claim 54 prior art of record fail to teach or fairly suggest a method of monitoring arterial pulse volume and deriving a signal in response to a physical, pharmacological agent, mental stressor or stimulus.

69. Referring to claim 61 prior art of record fail to teach or fairly suggest a method of measuring arterial blood volume, wherein detecting changes in the pulsatile arterial blood volume at multiple measurement sites comprises viewing variations in a peripheral arterial tone signal.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zoe E. Baxter whose telephone number is 571-272-8964. The examiner can normally be reached on Monday-Friday 7:30am-4:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor II can be reached on 571-272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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